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(54) Title: DEVICES, SYSTEMS, AND METHODS FOR RETAINING A NATIVE HEART VALVE LEAFLET

(57) Abstract: Devices, systems and methods retain a native heart valve leaflet to prevent retrograde flow. The devices, systems, and methods employ an implant that, in use, rests adjacent a valve annulus and includes a retaining structure that is sized and shaped to overlay at least a portion of one or more native valve leaflets. The retaining structure retains the leaflet or leaflets it overlays, to resist leaflet eversion and/or prolapse. In this way, the implant prevents or reduces regurgitation. The implant does not interfere significantly with the opening of and blood flow through the leaflets during periods of antegrade flow.

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**DEVICES, SYSTEMS, AND METHODS FOR
RETAINING A NATIVE HEART VALVE LEAFLET**

Related Applications

This application claims the benefit of co-
5 pending United States Patent Application Serial No.
09/666,617, filed September 20, 2000 and entitled "Heart
Valve Annulus Device and Methods of Using Same," which is
incorporated herein by reference. This application also
claims the benefit of Patent Cooperation Treaty
10 Application Serial No. PCT/US 02/31376, filed October 1,
2002 and entitled "Systems and Devices for Heart Valve
Treatments," which claimed the benefit of United States
Provisional Patent Application Serial No. 60/326,590,
filed October 1, 2001, which are incorporated herein by
15 reference. This application also claims the benefit of
United States Provisional Application Serial No.
60/429,444, filed November 26, 2002, and entitled "Heart
Valve Remodeling Devices;" United States Provisional
Patent Application Serial No. 60/429,709, filed November
20 26, 2002, and entitled "Neo-Leaflet Medical Devices;" and
United States Provisional Patent Application Serial No.
60/429,462, filed November 26, 2002, and entitled "Heart
Valve Leaflet Retaining Devices," which are each
incorporated herein by reference.

25 Field of the Invention

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The invention is directed to devices, systems, and methods for improving the function of a heart valve, e.g., in the treatment of mitral valve regurgitation.

Background of the Invention

5 I. The Anatomy of a Healthy Heart

The heart (see Fig. 1B) is slightly larger than a clenched fist. It is a double (left and right side), self-adjusting muscular pump, the parts of which work in unison to propel blood to all parts of the body.
10 The right side of the heart receives poorly oxygenated ("venous") blood from the body from the superior vena cava and inferior vena cava and pumps it through the pulmonary artery to the lungs for oxygenation. The left side receives well-oxygenation ("arterial") blood from
15 the lungs through the pulmonary veins and pumps it into the aorta for distribution to the body.

The heart has four chambers, two on each side -- the right and left atria, and the right and left ventricles. The atria are the blood-receiving chambers,
20 which pump blood into the ventricles. A wall composed of membranous and muscular parts, called the interatrial septum, separates the right and left atria. The ventricles are the blood-discharging chambers. A wall composed of membranous and muscular parts, called the
25 interventricular septum, separates the right and left ventricles.

The synchronous pumping actions of the left and right sides of the heart constitute the cardiac cycle. The cycle begins with a period of ventricular relaxation, called ventricular diastole. The cycle ends
30 with a period of ventricular contraction, called ventricular systole.

The heart has four valves (see Figs. 1B and 1C) that ensure that blood does not flow in the wrong
35 direction during the cardiac cycle; that is, to ensure

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that the blood does not back flow from the ventricles into the corresponding atria, or back flow from the arteries into the corresponding ventricles. The valve between the left atrium and the left ventricle is the mitral valve. The valve between the right atrium and the right ventricle is the tricuspid valve. The pulmonary valve is at the opening of the pulmonary artery. The aortic valve is at the opening of the aorta.

At the beginning of ventricular diastole (i.e., ventricular filling) (see Fig. 1B), the aortic and pulmonary valves are closed to prevent back flow from the arteries into the ventricles. Shortly thereafter, the tricuspid and mitral valves open (as Fig. 1B shows), to allow flow from the atria into the corresponding ventricles. Shortly after ventricular systole (i.e., ventricular emptying) begins, the tricuspid and mitral valves close (see Fig. 1C) -- to prevent back flow from the ventricles into the corresponding atria -- and the aortic and pulmonary valves open -- to permit discharge of blood into the arteries from the corresponding ventricles.

The opening and closing of heart valves occur primarily as a result of pressure differences. For example, the opening and closing of the mitral valve occurs as a result of the pressure differences between the left atrium and the left ventricle. During ventricular diastole, when ventricles are relaxed, the venous return of blood from the pulmonary veins into the left atrium causes the pressure in the atrium to exceed that in the ventricle. As a result, the mitral valve opens, allowing blood to enter the ventricle. As the ventricle contracts during ventricular systole, the intraventricular pressure rises above the pressure in the atrium and pushes the mitral valve shut.

Fig. 1D shows a posterior oblique cutaway

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view of a healthy human heart 100. Two of the four heart chambers are shown, the left atrium 170, and the left ventricle 140 (not shown are the right atrium and right ventricle). The left atrium 170 fills with blood from the pulmonary veins. The blood then passes through the mitral valve (also known as the bicuspid valve, and more generally known as an atrioventricular valve) during ventricular diastole and into the left ventricle 140. During ventricular systole, the blood is then ejected out of the left ventricle 140 through the aortic valve 150 and into the aorta 160. At this time, the mitral valve should be shut so that blood is not regurgitated back into the left atrium.

The mitral valve consists of two leaflets, an anterior leaflet 110, and a posterior leaflet 115, attached to chordae tendineae 120 (or chords), which in turn are connected to papillary muscles 130 within the left atrium 140. Typically, the mitral valve has a D-shaped anterior leaflet 110 oriented toward the aortic valve, with a crescent shaped posterior leaflet 115. The leaflets intersect with the atrium 170 at the mitral annulus 190.

In a healthy heart, these muscles and their chords support the mitral and tricuspid valves, allowing the leaflets to resist the high pressure developed during contractions (pumping) of the left and right ventricles. In a healthy heart, the chords become taut, preventing the leaflets from being forced into the left or right atria and everted. Prolapse is a term used to describe the condition wherein the coaptation edges of each leaflet initially may coapt and close, but then the leaflets rise higher and the edges separate and the valve leaks. This is normally prevented by contraction of the papillary muscles and the normal length of the chords. Contraction of the papillary muscles is simultaneous with

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the contraction of the ventricle and serves to keep healthy valve leaflets tightly shut at peak contraction pressures exerted by the ventricle.

II. Characteristics and Causes of Mitral Valve Dysfunction

Valve malfunction can result from the chords becoming stretched, and in some cases tearing. When a chord tears, the result is a flailed leaflet. Also, a normally structured valve may not function properly because of an enlargement of the valve annulus pulling the leaflets apart. This condition is referred to as a dilation of the annulus and generally results from heart muscle failure. In addition, the valve may be defective at birth or because of an acquired disease, usually infectious or inflammatory.

Fig. 2 shows a cutaway view of a human heart 200 with a prolapsed mitral valve. The prolapsed valve does not form a tight seal during ventricular systole, and thus allows blood to be regurgitated back into the left atrium during ventricular contraction. The anterior 220 and posterior 225 leaflets are shown rising higher than normal (i.e., prolapsing) into the left atrium. The arrows indicate the direction of regurgitant flow. Among other causes, regurgitation can result from redundant valve leaflet tissue or from stretched chords 210 that are too long to prevent the leaflets from being blown into the atrium. As a result, the leaflets do not form a tight seal, and blood is regurgitated into the atrium.

Fig. 3 shows a cutaway view of a human heart 300 with a flailing mitral valve 320. The flailing valve also does not form a tight seal during ventricular systole. Blood thus regurgitates back into the left atrium during ventricular contraction, as indicated by the arrows. Among other causes, regurgitation can also result from torn chords 310.

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As a result of regurgitation, "extra" blood back flows into the left atrium. During subsequent ventricular diastole (when the heart relaxes), this "extra" blood returns to the left ventricle, creating a
5 volume overload, i.e., too much blood in the left ventricle. During subsequent ventricular systole (when the heart contracts), there is more blood in the ventricle than expected. This means that: (1) the heart must pump harder to move the extra blood; (2) too little
10 blood may move from the heart to the rest of the body; and (3) over time, the left ventricle may begin to stretch and enlarge to accommodate the larger volume of blood, and the left ventricle may become weaker.

Although mild cases of mitral valve
15 regurgitation result in few problems, more severe and chronic cases eventually weaken the heart and can result in heart failure. Mitral valve regurgitation can be an acute or chronic condition. It is sometimes called mitral insufficiency.

20 III. Prior Treatment Modalities

In the treatment of mitral valve regurgitation, diuretics and/or vasodilators can be used to help reduce the amount of blood flowing back into the left atrium. An intra-aortic balloon counterpulsation
25 device is used if the condition is not stabilized with medications. For chronic or acute mitral valve regurgitation, surgery to repair or replace the mitral valve is often necessary.

To date, invasive, open heart surgical
30 approaches have been used to repair or replace the mitral valve with either a mechanical valve or biological tissue (bioprosthetic) taken from pigs, cows or horses.

The need remains for simple, cost-effective,
and less invasive devices, systems, and methods for
35 treating dysfunction of a heart valve, e.g., in the

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treatment of mitral valve regurgitation.

Summary of the Invention

The invention provides devices, systems and methods that retain a native heart valve leaflet. The devices, systems, and methods include an implant that, in use, rests adjacent all or a portion of a valve annulus. The implant includes a retaining structure that is shaped to overlay at least a portion of one or more native valve leaflets. The implant further includes spaced-apart struts sized and configured to contact tissue near or within the heart valve annulus. The struts brace the retaining structure to resist leaflet eversion and/or prolapse. In this way, the implant prevents or reduces retrograde flow and regurgitation. The implant does not interfere with the opening of and blood flow through the leaflets during antegrade flow.

Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

Description of the Drawings

Fig. 1A is a perspective, anterior anatomic view of the interior of a healthy heart.

Fig. 1B is a superior anatomic view of the interior of a healthy heart, with the atria removed, showing the condition of the heart valves during ventricular diastole.

Fig. 1C is a superior anatomic view of the interior of a healthy heart, with the atria removed, showing the condition of the heart valves during ventricular systole.

Fig. 1D is a posterior oblique cutaway view of a portion of a human heart, showing a healthy mitral valve during ventricular systole, with the leaflets properly coapting.

Fig. 2 is a posterior oblique cutaway view of

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a portion of a human heart, showing a dysfunctional mitral valve during ventricular systole, with the leaflets not properly coapting, causing regurgitation.

5 Fig. 3 is a posterior oblique cutaway view of a portion of a human heart, showing a dysfunctional mitral valve during ventricular systole, with the leaflets flailing, causing regurgitation.

Fig. 4 is a perspective, anatomic view of a wire form implant that includes a retaining element to resist eversion and/or prolapse of a native valve
10 leaflet, the implant being shown installed on a mitral valve annulus.

Fig. 5 is a side elevation view of the implant shown in Fig. 4, shown outside of the body.

15 Fig. 6 is a top view of the implant shown in Fig. 4, shown outside the body.

Fig. 7 is a top view of another illustrative wire form implant of the type shown in Fig. 6.

Figs. 8 and 9 are top views of illustrative
20 wire form implants of the type shown in Figs. 4 and 5, which include retaining elements to resist eversion and/or prolapse of a native valve leaflet, and which also include both infra-annular struts and tabs and supra-annular pads to fix the position of the implants in a
25 valve annulus.

Fig. 10 is a perspective view of the implant shown in Fig. 9.

Fig. 11 is a perspective, anatomic view of the wire form implant shown in Fig. 10, the implant being
30 shown installed on a mitral valve annulus.

Figs. 12 to 14 are perspective, anatomic views showing the intravascular introduction and deployment of the implant shown in Fig. 11 on a mitral valve annulus.

35 Fig. 15 is a perspective view of an

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illustrative wire form implant of the type shown in Figs. 4 and 5, which include retaining elements to resist eversion and/or prolapse of a native valve leaflet, and which also include frameworks to orient and stabilize the position of the implants in a valve annulus.

Fig. 16 is a top view of wire-form mesh implant that resists eversion and/or prolapse of a native valve leaflet.

Fig. 17 is a perspective, anatomic view of the wire-form mesh implant shown in Fig. 16 installed on a mitral valve annulus.

Figs. 18 and 19 are top views of illustrative embodiments of implants of the types shown in Figs. 5 and 6, showing implants that are narrow and do not peripherally rest on the entire valve annulus.

Fig. 20 is a top view of an illustrative embodiment of a wire-form mesh implant of the type shown in Figs. 16 and 17, being shown in a flattened condition for intravascular deployment, which, upon deployment, resists eversion and/or prolapse of a native valve leaflet, and which also include an auxiliary structure to orient and stabilize the position of the implants in a valve annulus, the implant in Fig. 20 also including infra-annular struts and tabs to fix the position of the implant in the valve annulus.

Fig. 21 is a perspective, anatomic view of the wire-form mesh implant shown in Fig. 20, installed on a mitral valve annulus.

Figs. 22, 23, and 24 are top views of illustrative embodiments of wire-form mesh implants of the type shown in Fig. 20, which resist eversion and/or prolapse of a native valve leaflet, and which also include a combination of auxiliary structures and infra-annular struts and tabs to fix, orient, and stabilize the position of the implants in a valve annulus, the implants

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being shown in a flattened condition for intravascular deployment.

Fig. 25 is a perspective view of illustrative embodiments of wire-form mesh implants of the type shown in Fig. 20, which resist eversion and/or prolapse of a native valve leaflet, and which also include a combination of auxiliary structures and infra-annular struts and tabs to fix, orient, and stabilize the position of the implants in a valve annulus, the implants being shown in an expanded condition after intravascular deployment.

Detailed Description

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention, which may be embodied in other specific structure. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

I. Implants for Retaining a Native Heart Valve Implant

A. Planar Wire-Form Implants

1. Overview

Figs. 4, 5, and 6 show an implant 400 sized and configured to retain at least one dysfunctional native heart valve leaflet. In use (see, in particular, Fig. 4), the implant 400 rests adjacent all or a portion of the native heart valve annulus, which, in Fig. 4, is in the atrium. The implant 400 includes a scaffold 410, at least a portion of which defines a pseudo-annulus. The scaffold 410 includes a retaining element 420 at or near the pseudo-annulus. The retaining element 420 is sized and shaped to overlay at least a portion of the

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superior surface at least one native valve leaflet. The implant 400 allows the native leaflets to coexist with the implant 400.

In its most basic form, the components of the
5 implant 400 are made -- e.g., by bending, shaping, joining, machining, molding, or extrusion -- from a biocompatible metallic or polymer material, or a metallic or polymer material that is suitably coated, impregnated, or otherwise treated with a material or combination of
10 materials to impart biocompatibility. The material is also desirably radio-opaque to facilitate fluoroscopic visualization. The implant material may be rigid, semi-rigid, or flexible.

In the embodiment shown in Fig. 4, the
15 scaffold 410 is sized and configured to rest adjacent all or a portion of the mitral annulus in the atrium. In the illustrated embodiment (Fig. 4), the scaffold 410 forms an annular body that, at least in part, approximates the shape of the native annulus. For this reason, at least a
20 portion of the scaffold 410 is said to define a pseudo-annulus. The scaffold 410 includes the retaining element 420, which extends from the periphery of the scaffold 410 radially into the pseudo-annulus.

The retaining element 420 is sized and
25 configured (see Fig. 4) to overlay the superior surface of at least one native valve leaflet. In the illustrated embodiment, the retaining element 420 overlays regions of both leaflets. However, the retaining element 420 could be sized, configured, and oriented to overlay all or a
30 portion of one leaflet or both leaflets. The size, configuration, and orientation of the retaining element 420 can vary, depending on patient needs, as will be described in greater detail later.

When installed adjacent a mitral valve
35 annulus, during ventricular systole the retaining element

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420 exerts a restraining force on the superior surface of the leaflet or leaflets it overlays, resisting deflection of the leaflet or leaflets into the atrium and preventing leaflet eversion and/or prolapse as well as retrograde
5 flow of blood through the valve during ventricular systole from the ventricle into the atrium. The restraining force also serves to keep valve leaflets tightly shut during peak ventricular systolic pressures. The retaining element 420 thus serves as a "backstop" for
10 the leaflet or leaflets it overlays. During ventricular diastole this restraining force goes to zero and the retaining element 420 does not prevent opening of the native valve leaflet or leaflets during antegrade flow. During ventricular diastole, the native valve leaflet or
15 leaflets open normally so that blood flow occurs from the atrium into the ventricle. The implant 400 thereby restores normal one-way function to the valve.

As shown in Figs. 5 and 6, in the illustrated embodiment, the scaffold 410 and the retaining element
20 420 are shaped from a continuous length of wire-formed material. The shape and materials of the scaffold 410 and retaining element 420 provide the implant 400 with spring-like characteristics. The retaining element 420 is shaped so that, during ventricular systole, it
25 elastically resists eversion and/or prolapse of the leaflet or leaflets.

2. Fixation of Implants

The spring-like bias of the implant 400 facilitates compliant fixation of the outer periphery of
30 the implant 400 to or near the annulus. The scaffold 410 of the implant 400 dynamically conforms to the shape of the anatomy.

As Figs. 5 and 6 show, the scaffold 410 can also include supra-annular contact structures 440. The
35 structures 440 are appended to the scaffold 410 to

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provide multiple contact regions between the implant 400 and the atrial wall, above the valve annulus. The multiple regions of contact that the structures 440 provide uniformly distributes the resting forces of the implant, and help to prevent erosion of the atrial walls and migration of the implant.

Alternatively or in combination with the supra-annular structures 440, the implant 400 can include infra-annular contact struts 430. The struts 430 are appended to the scaffold 410, extending below the plane of the annulus into the ventricular chamber. The struts 430 are preferably configured to extend through the valve orifice on narrow connecting members, so that they will not interfere with the opening and closing of the valve. The struts 430 fix and stabilize the implant within the annulus.

In this arrangement, the struts 430 are desirably sized and configured to contact tissue near or within the mitral valve annulus to brace the retaining structure 420 to resist leaflet eversion and/or prolapse during ventricular systole. In this arrangement, it is also desirable that the scaffold 410 be "elastic," i.e., the material of the scaffold 410 is selected to possess a desired spring constant. This means that the scaffold 410 is sized and configured to possess a normal, unloaded, shape or condition, in which the scaffold 410 is not in net compression, and the struts 450 are spaced apart farther than the longest cross-annulus distance between the tissue that the struts 430 are intended to contact. In the illustrated embodiment (Fig. 4), the scaffold 410 shown resting along the major (i.e., longest) axis of the mitral valve annulus, with the struts 430 contact tissue at or near the leaflet commissures. However, other orientations are possible. The struts 430 need not rest at or near the leaflet commissures, but may be

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significantly removed from the commissures, so as to gain padding from the leaflets. The spring constant imparts to the scaffold 410 the ability to be elastically compressed out of its normal, unloaded condition, in response to external compression forces applied at the struts 430. The scaffold 410 is sized and configured to assume an elastically loaded, in net compression condition, during which the struts 430 are spaced apart a sufficiently shorter distance to rest in engagement with tissue at or near the leaflet commissures (or wherever tissue contact with the struts 430 is intended to occur) (see Figs. 9A or 9B). When in its elastically loaded, net compressed condition (see Figs. 9A and 9B), the scaffold 410 can exert forces to the tissues through the struts 430. These forces hold the scaffold 410 (and thus the retaining element 420 itself) against migration within the annulus. Furthermore, when the struts 430 are positioned at or near the commissures, they tend to outwardly displace tissue and separate tissue along the major axis of the annulus, which also typically stretches the leaflet commissures, shortens the minor axis, and/or reshapes surrounding anatomic structures. The scaffold 410 can also thereby reshape the valve annulus toward a shape more conducive to leaflet coaptation. It should be appreciated that, in order to be therapeutic, the implant 400 may only need to reshape the annulus during a portion of the heart cycle, such as during ventricular systolic contraction. For example, the implant may be sized to produce small or negligible outward displacement of tissue during ventricular diastole when the tissue is relaxed, but restrict the inward movement of tissue during ventricular systolic contraction.

As just described, different forms of heart valve treatment can be provided using a single implant 400.

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Implants having one or more of the technical features just described, to thereby function *in situ* as a backstop or retainer for native leaflets, may be sized and configured in various ways. Various illustrative
5 embodiments will now be described.

Fig. 7 shows another illustrative embodiment of an implant 400 including a scaffold 410 that defines a pseudo-annulus and a retaining element 420 that functions as a leaflet retainer 420. In Fig. 7, the implant 400 is
10 shown in a flattened condition. The implant 400 includes infra-annular struts 430. Upon deployment, the struts 430 contact tissue near or within the heart valve annulus, and, in particular, between or nearly between the commissures of the leaflets, and extend into the
15 ventricular side of the valve. As before described, the struts 430 function to brace and secure the implant *in situ*.

Fig. 8 shows yet another illustrative embodiment of an implant 400 including a scaffold 410
20 that defines a pseudo-annulus and a retaining element 420 that functions as a leaflet retainer. The implant 400 also includes infra-annular struts 430. In addition, the implant 400 includes supra-annular contact structures 440, used to disperse the loads experienced by the
25 implant throughout the atrium.

Fig. 9 shows other illustrative embodiment of an implant 400 including a scaffold 410 that defines a pseudo-annulus and a retaining element 420 that functions as a leaflet retainer. In Figs. 8 and 9, the retaining
30 element 420 extends across the interior of the implant in a figure eight pattern and has two support struts 430. Like the implant shown in Fig. 8, the implant 400 in Fig. 9 includes a plurality of infra-annular struts 430 and a plurality of supra-annular contact structures 440 that
35 brace, fix, and stabilize the implants *in situ*.

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As can be seen in the perspective view in Fig. 10, one or more of the struts 430 can include a superior component that rests on the atrial side of the valve, and an inferior component that rests on the ventricular side of the valve (see Fig. 11). In this arrangement, the struts 430 place the implant near or within a heart valve annulus, e.g., between the commissures of the leaflets. As before described, the shape and tension of the scaffold 410 can apply a force through the struts 430 that outwardly displaces tissue and stretches the annulus. The displacement of the tissue can remodel the annulus and promote normal valve function, free of eversion and/or prolapse, through a different mechanism than the retaining elements 420.

Any number of supra-annular contact structures 440 can also be used, to disperse the loads experienced by the implant throughout the atrium.

As Fig. 15 shows, a given implant 400 can include one or more auxiliary structures 450 to orient and stabilize the implant 400 within the left atrium. In Fig. 15, the implant 400 includes, in addition to the scaffold 410 and the retaining element 420, an orientation and stabilization framework 450. The framework 450 rises from the scaffold 410 above the retaining element 420, e.g., with two substantially parallel arched wires, which connect to form a semicircular hoop above the restraining element 420. The framework 450 helps to accurately position the implant 400 within the atrium, and also helps to secure the implant 400 within the atrium.

Preferably the framework 450 does not interfere with atrial function, but instead is compliant enough to contract with the atrium. As such, the implant 400 may have nonuniform flexibility to improve its function within the heart.

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Additionally, the implant 400 of Fig. 15 has infra-annular struts 430 that contact tissue near or within the heart valve annulus to brace the implant 400 and assist in positioning and anchoring of the implant.

5 The implant 400 may be additionally fixed to the annulus in various auxiliary ways. For example, the implant 400 may be secured to the annulus with sutures or other attachment means (i.e. barbs, hooks, staples, etc.). Still, the position and orientation of the
10 implant is desirably braced or fixed by structures appended to or carried by the implant itself, obviating reliance upon such auxiliary fixation measures.

 In Fig. 15, the retaining element 420 is sized and configured to cover the superior surface of a single
15 leaflet.

 Figs. 18 and 19 show other illustrative embodiments of implants 400 sized and configured to function as leaflet retainers. In these embodiment, each implant 400 includes a narrow leaflet retaining element
20 420. The narrow leaflet retaining elements 420 span the annulus, but the associated scaffold 410 need not peripherally follow the entire annulus.

3. Deployment of Wire Form Implants

 The implant 400 may be delivered
25 percutaneously, thoracoscopically through the chest, or using open heart surgical techniques. If delivered percutaneously, the implant 400 may be made from a superelastic material (for example superelastic Nitinol alloy) enabling it to be folded and collapsed such that
30 it can be delivered in a catheter, and will subsequently self-expand into the desired shape and tension when released from the catheter. The deployment of an implant in this fashion will now be described.

 Figs. 12 to 14 show a sequence of steps for a
35 catheter-based, percutaneous deployment of an implant 400

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having the technical features described. Percutaneous vascular access is achieved by conventional methods into the femoral or jugular vein. Under image guidance (e.g., fluoroscopic, ultrasonic, magnetic resonance, computed tomography, or combinations thereof), a first catheter (not shown) is steered through the vasculature into the right atrium. A needle cannula carried on the distal end of the first catheter is deployed to pierce the septum between the right and left atrium. A guide wire 1710 is advanced trans-septally through the needle catheter into the left atrium. The first catheter is withdrawn, leaving the guide wire 1710 behind. Fig. 12 shows the guide wire 1710 introduced through the vena cava 1730 and into the right atrium, and then through the septum 1720 between the right and left atriums, into the left atrium.

As Fig. 13 shows, under image guidance, an implant delivery catheter 1820 is advanced over the guide wire 1710 into the left atrium into proximity with the mitral valve. Alternatively, the implant delivery catheter 58 can be deployed trans-septally by means of surgical access through the right atrium.

The implant delivery catheter 1820 carries within it a wire-form implant 400 of a type shown in Figs. 10 and 11, previously described. The implant 10 is constrained within the catheter 1820 in a collapsed, straightened condition. A push rod within the catheter 1820 expels the implant (see Fig. 13). Free of the catheter 1820, the implant 400 will expand, as Fig. 14 shows. Progressively freed from the catheter 1820, the implant 400 shapes and seats about the annulus, as the struts 430 seat within the commissures and the retaining elements 420 extend over the leaflets. The implant can also be positioned or repositioned under image guidance within the left atrium using a catheter-deployed grasping instrument.

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B. Wire-Form Mesh Implants

Figs. 16 and 17 show another embodiment of an implant 400 including a scaffold 410 that defines a pseudo-annulus and a retaining element 420 that functions as a leaflet retainer. In this embodiment, the retaining element 420 includes wire-form mesh that has been shaped to fit the heart anatomy (see Fig. 16). The wire-form mesh can be secured within the atrium with sutures or other attachment means (i.e. barbs, hooks, staples, etc.). Alternatively, the body of the wire-form mesh can be secured by spring action between the body of the implant and the walls of the heart.

In Fig. 20, another illustrative embodiment of an implant 400 including a scaffold 410 that defines a pseudo-annulus and a retaining element 420. The implant 400 is shown in a flattened out condition. Fig. 21 shows the implant 400 shown in Fig. 20 after deployment in a left atrium. The implant 400 includes a leaflet retaining element 420, upwardly extending stabilization arch structures 440, as well as infra-annular struts 430, shaped and configured as previously described. The arch structures 440 and struts 430 cooperate to orient and stabilize the implant in the desired position for retaining the valve leaflets.

Figs. 22, 23, and 24 show illustrative embodiments of other implants 400 of the type shown in Figs. 20 and 21 in flattened out conditions. Each of these implants 400 include a scaffold 410 that defines a pseudo-annulus and a retaining element 420. In these embodiments, the implants 400 include, in addition to a leaflet retaining element 420, a plurality of arch structures 440 that, when deployed, contact the interior of the atrium to support and align the implant 400, as well as infra-annular struts 430 that contact tissue near or within the heart valve annulus to brace the retaining

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structure 420 to resist leaflet eversion and/or prolapse during ventricular systole. Fig. 25 shows various illustrative embodiments of an implant 400 in a deployed conditioned.

5 While the new devices and methods have been more specifically described in the context of the treatment of a mitral heart valve, it should be understood that other heart valve types can be treated in the same or equivalent fashion. By way of example, and
10 not by limitation, the present systems and methods could be used to resist or prevent retrograde flow in any heart valve annulus, including the tricuspid valve, the pulmonary valve, or the aortic valve. In addition, other embodiments and uses of the invention will be apparent to
15 those skilled in the art from consideration of the specification and practice of the invention disclosed herein. The specification and examples should be considered exemplary and merely descriptive of key technical features and principles, and are not meant to
20 be limiting. The true scope and spirit of the invention are defined by the following claims. As will be easily understood by those of ordinary skill in the art, variations and modifications of each of the disclosed embodiments can be easily made within the scope of this
25 invention as defined by the following claims.

- 21 -

What is claimed is:

1. An implant that retains a native heart valve leaflet to resist retrograde flow comprising a scaffold sized and configured to rest adjacent all or a
5 portion of a native heart valve annulus, at least a portion of the scaffold defining a pseudo-annulus and including a retaining structure near or within the pseudo-annulus that is sized and shaped to overlay at least a portion of one or more native valve leaflets, the
10 scaffold further including spaced-apart struts sized and configured to contact tissue near or within the heart valve annulus to brace the retaining structure to resist leaflet eversion and/or prolapse.
2. An implant according to claim 1
15 wherein the retaining structure comprises a wire-form structure.
3. An implant according to claim 1
wherein at least one of the struts comprises a wire-form structure.
- 20 4. An implant according to claim 1
wherein the retaining structure and the struts each comprises a wire-form structure.
5. An implant according to claim 1
wherein the scaffold is collapsible for
25 placement within a catheter.
6. An implant according to claim 1
wherein at least one of the struts carries a structure sized and configured to increase a surface area of contact with tissue at, above, or below the annulus.
- 30 7. An implant according to claim 1
further including at least one structure appended to the scaffold and being sized and configured to contact tissue at, above, or below the heart valve annulus to stabilize the scaffold.
- 35 8. An implant according to claim 1

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wherein the scaffold includes a material and a shape to provide a spring-like bias to enable compliant contact with tissue near or within the heart valve annulus.

- 5 9. An implant according to claim 1
 wherein the struts reshape the heart valve
annulus. 10. An implant according to claim 1
 wherein the struts apply tension to tissue to
reshape the heart valve annulus.
- 10 11. An implant according to claim 1
 wherein the struts displace tissue to reshape
the heart valve annulus.
12. An implant according to claim 1
 further including a second heart valve
15 treatment element appended to the scaffold to affect a
heart valve function.
13. An implant according to claim 12
 wherein the second heart valve treatment
element includes means for reshaping the heart valve
20 annulus for leaflet coaptation.
14. An implant according to claim 12
 wherein the second heart valve treatment
element includes means for separating tissue along an
axis of the heart valve annulus for leafleted coaptation.
- 25 15. A method for retaining a native heart
leaflet to resist retrograde flow comprising the steps of
 introducing an implant as defined in claim 1
into a heart, and
- 30 resisting leaflet eversion and/or prolapse by
locating the scaffold as defined in claim 1 adjacent all
or a portion of a native heart valve annulus to define a
pseudo-annulus with the retaining structure as defined in
claim 1 overlaying at least a portion of one or more
35 native valve leaflets and with the spaced-apart struts as

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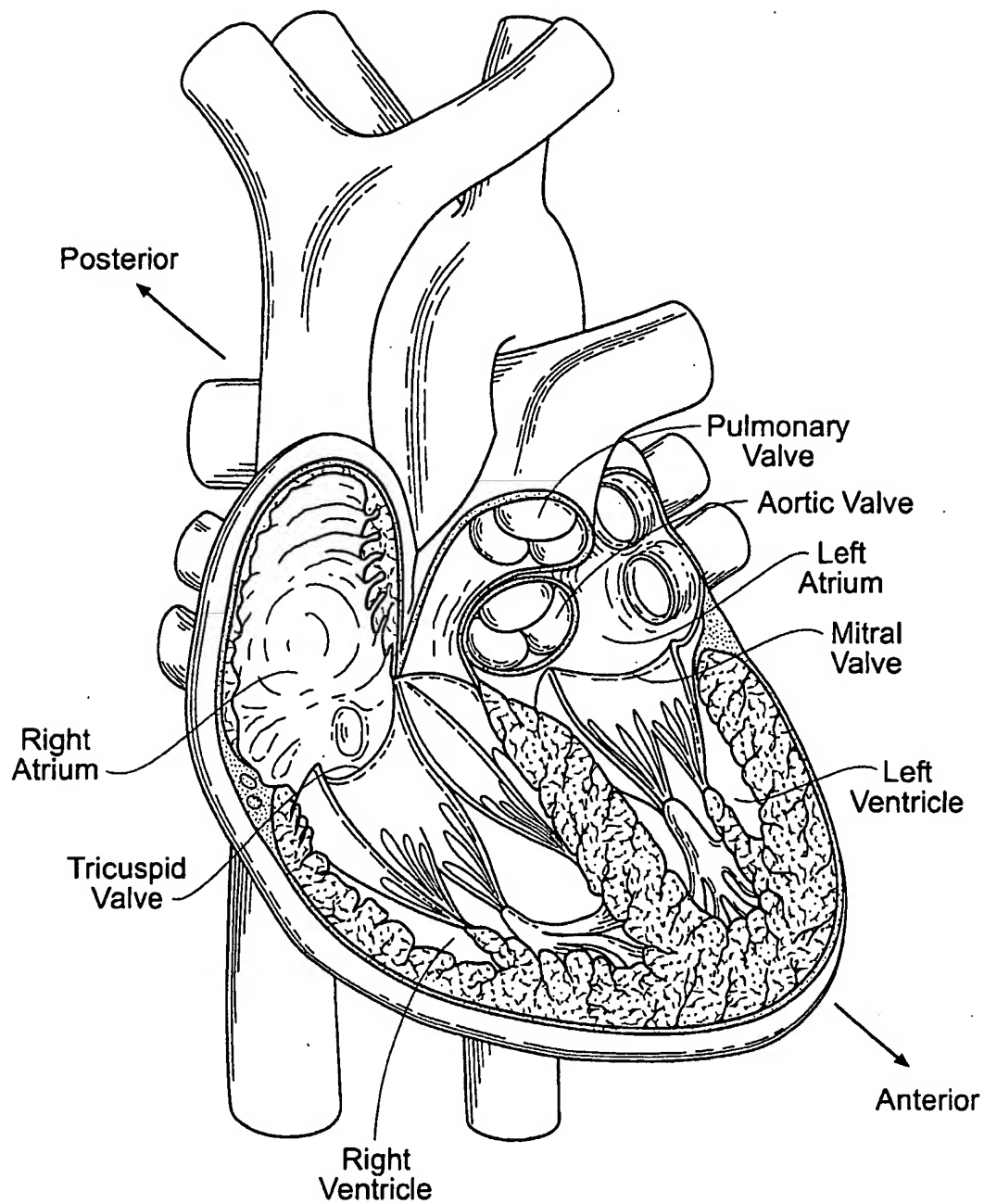
defined in claim 1 contacting tissue near or within the heart valve annulus to brace the retaining structure.

16. A method according to claim 15
wherein the introducing step comprises using
5 an open heart surgical procedure.

17. A method according to claim 15
wherein the introducing step comprises using a surgical procedure in which the implant is carried within a catheter.

10 18. A method according to claim 15
wherein the introducing step comprises using an intravascular surgical procedure.

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*Fig. 1*

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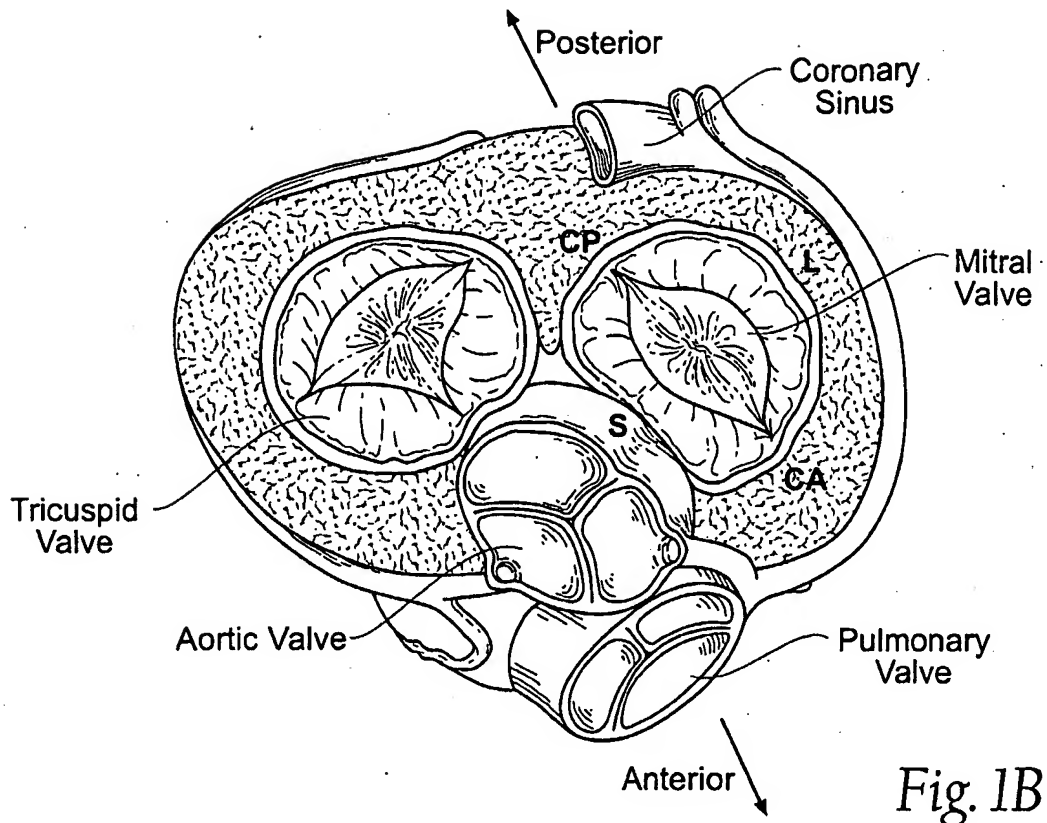


Fig. 1B

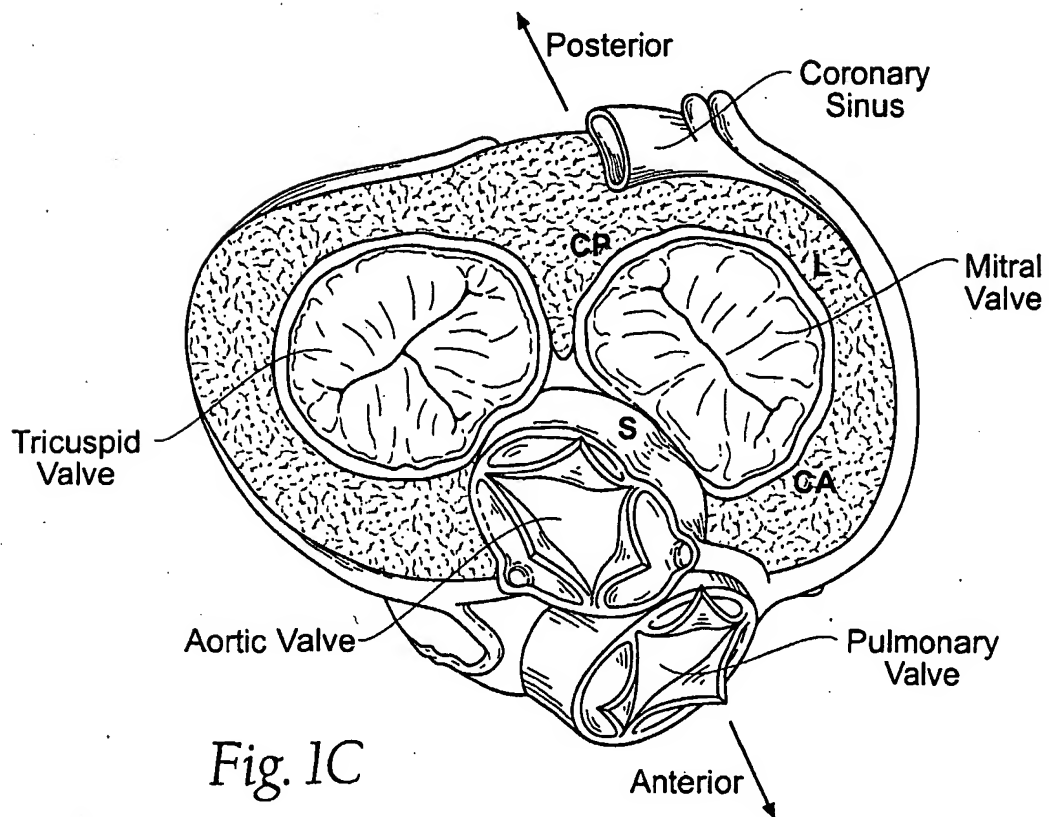
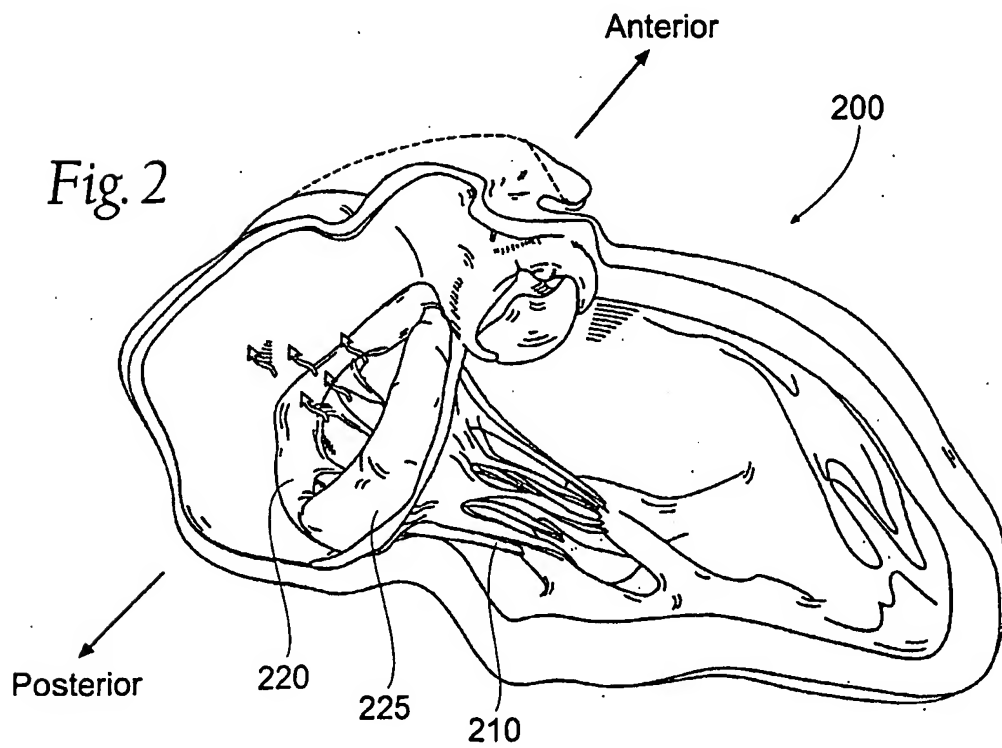
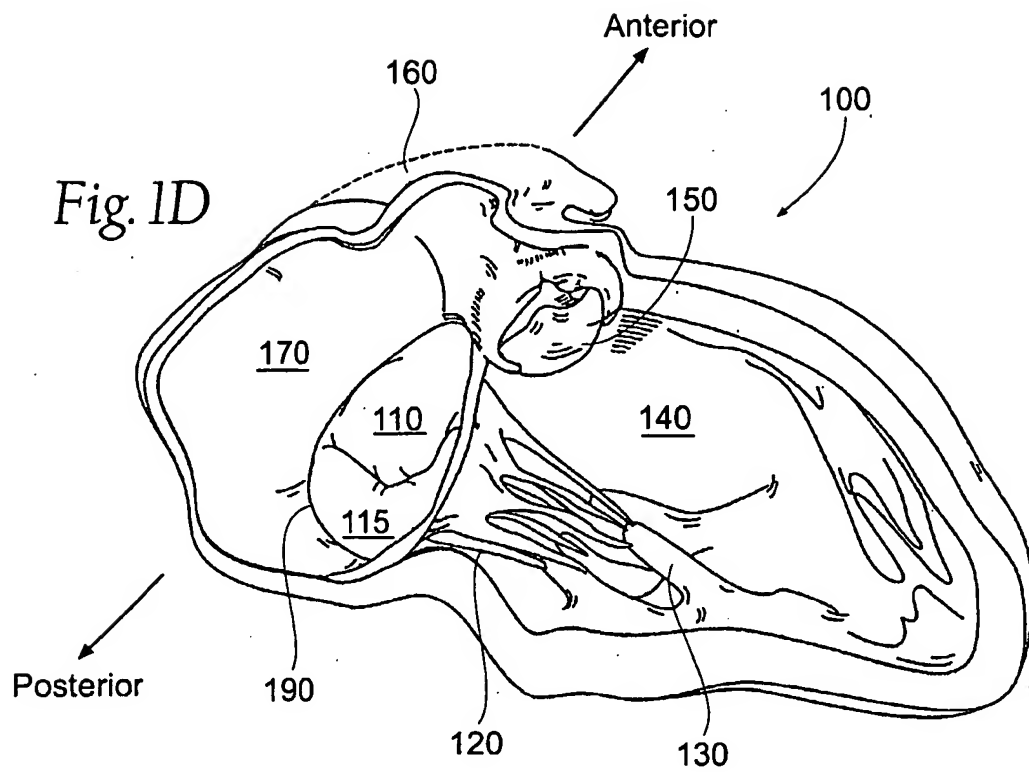


Fig. 1C



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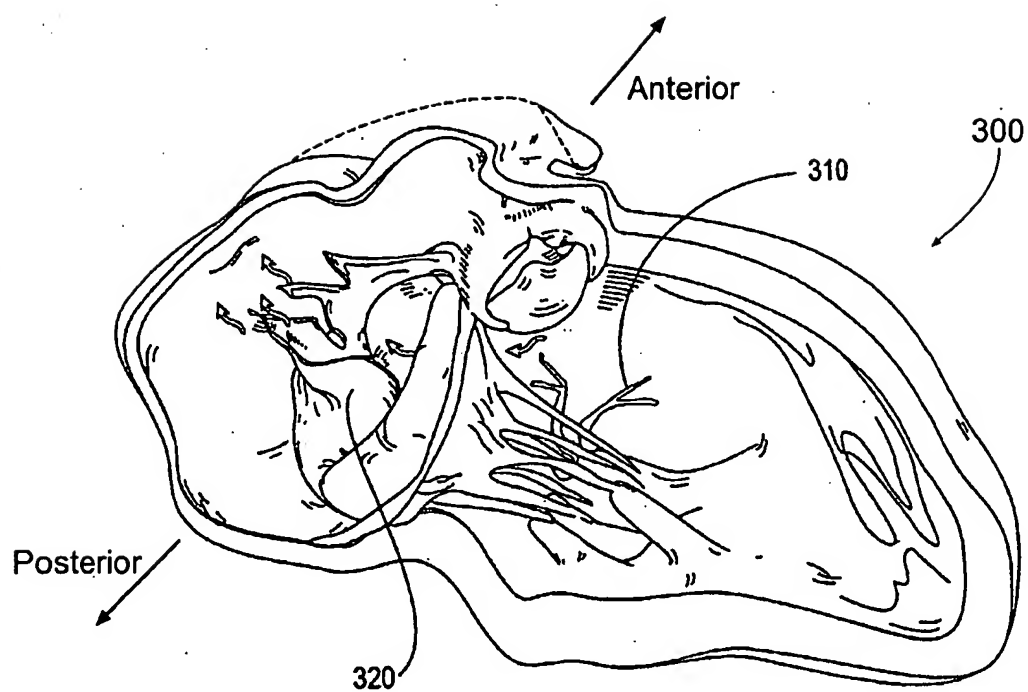
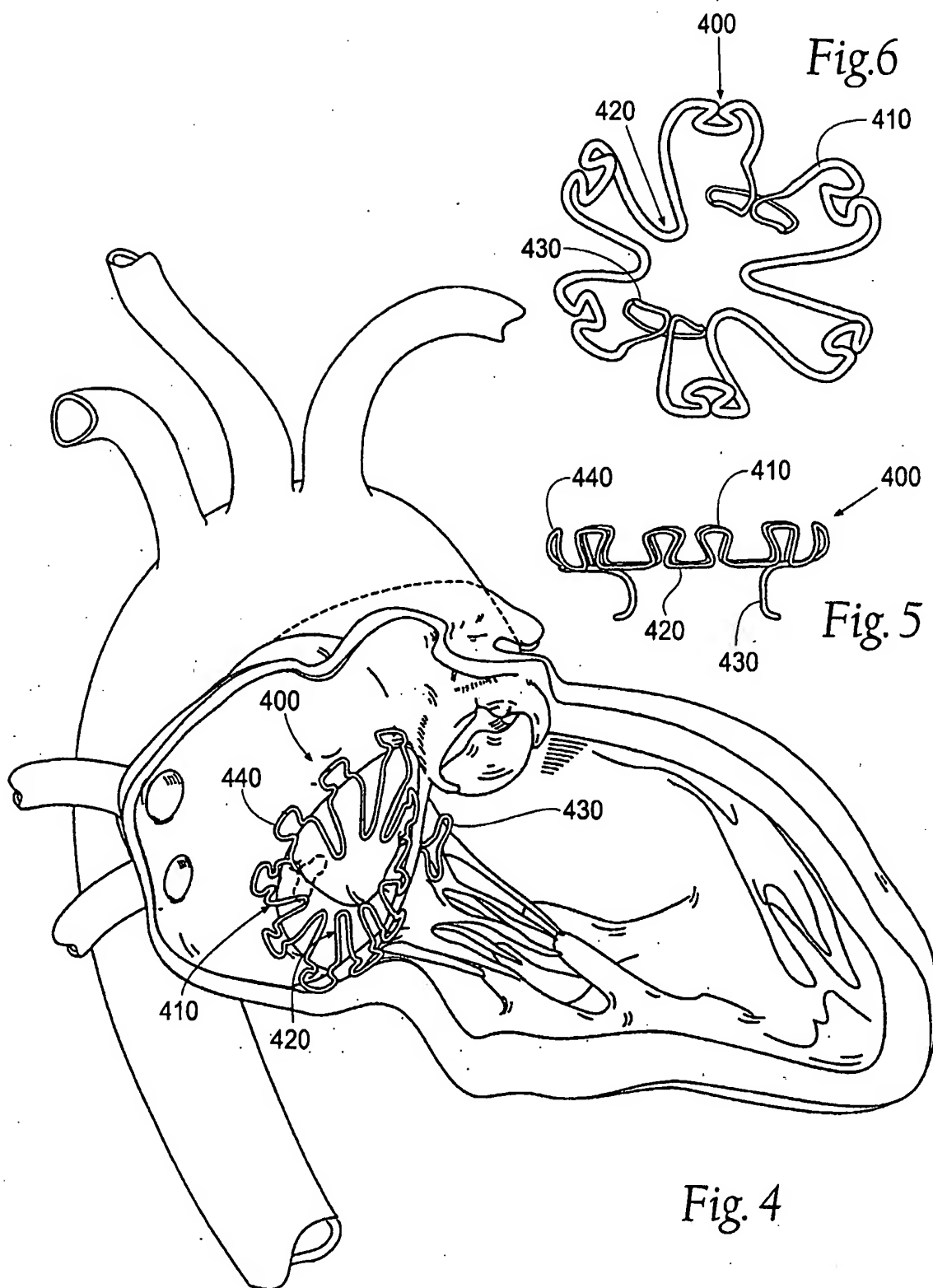
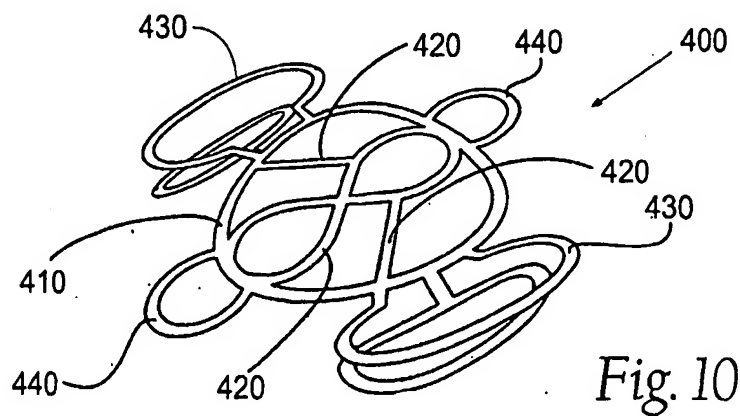
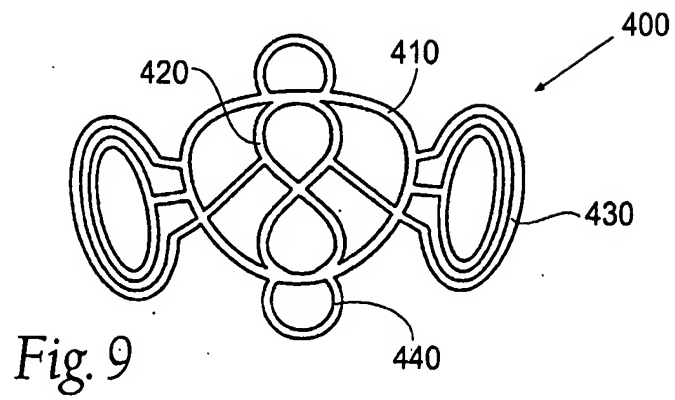
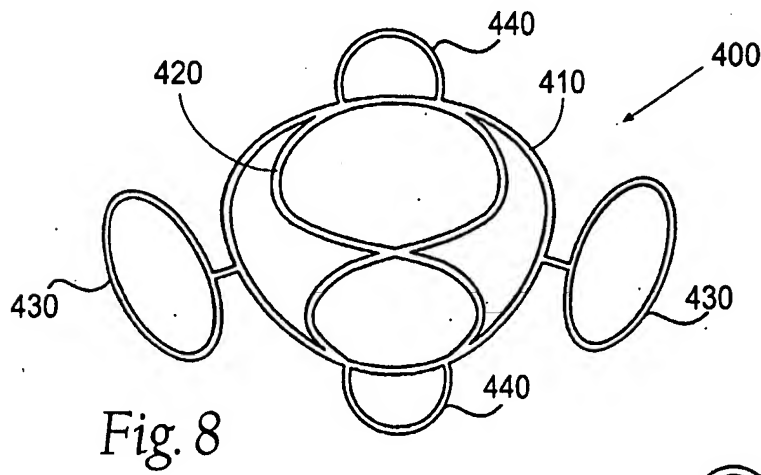
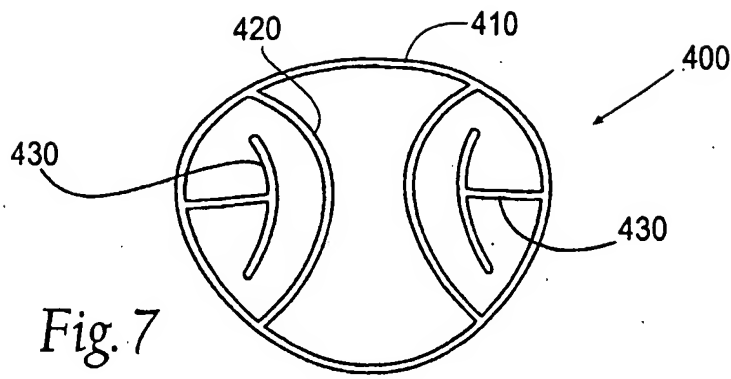


Fig. 3





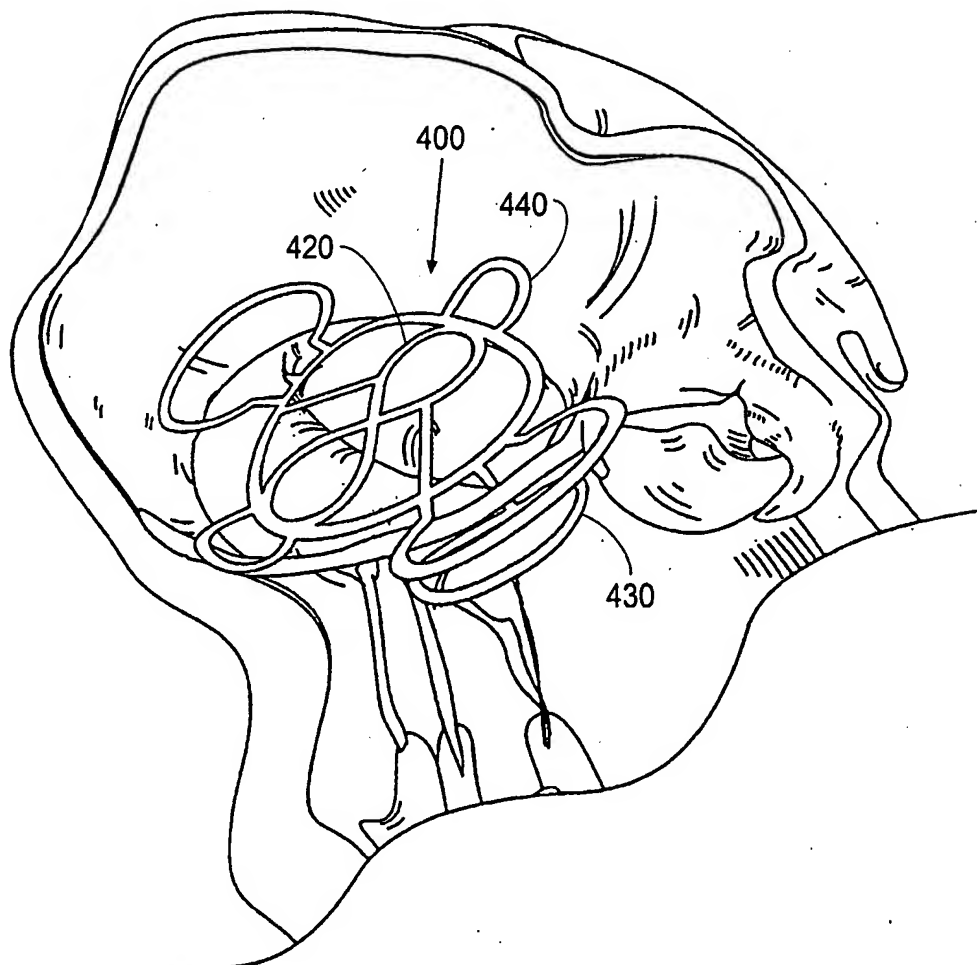


Fig. 11

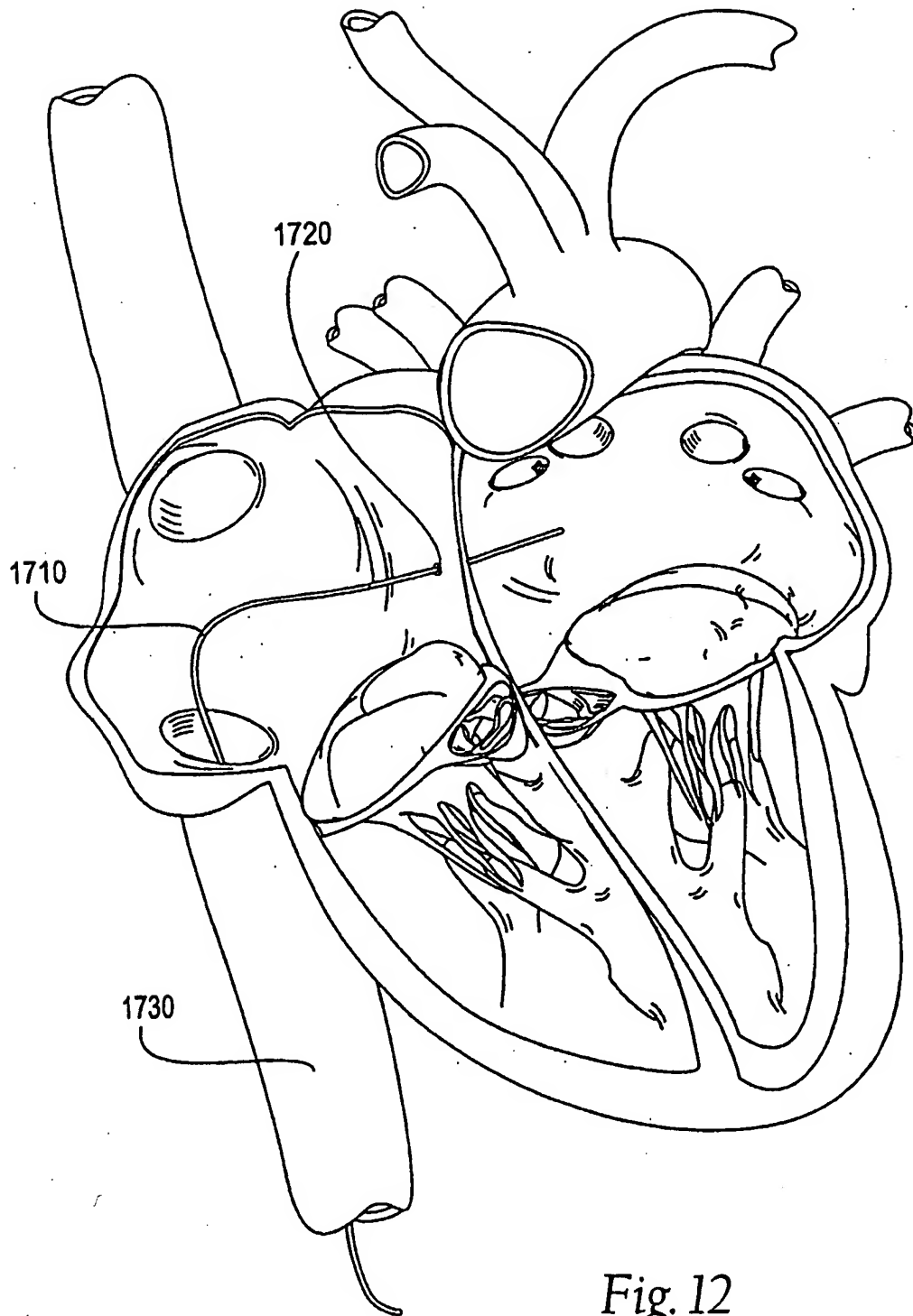


Fig. 12

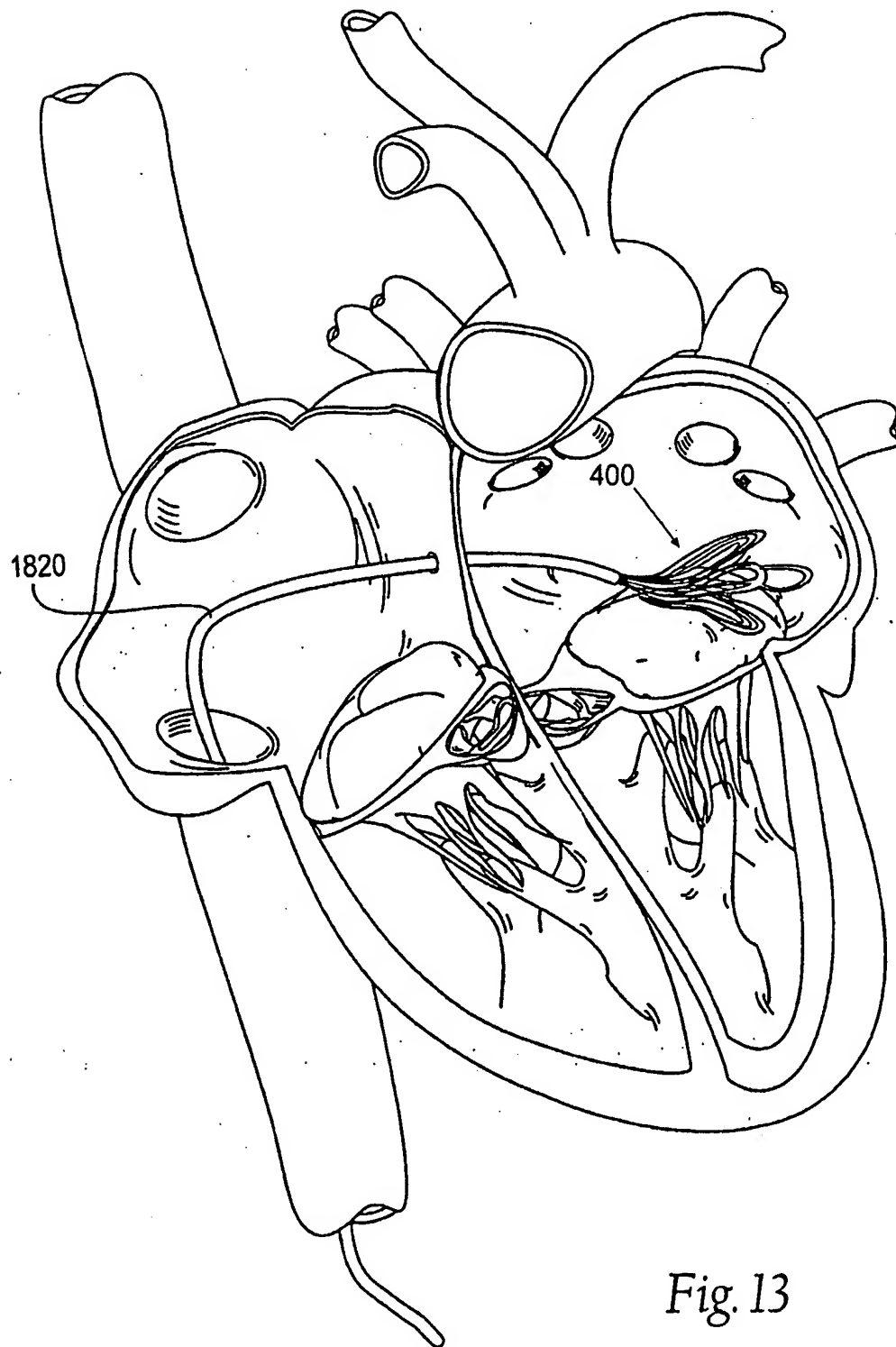


Fig. 13

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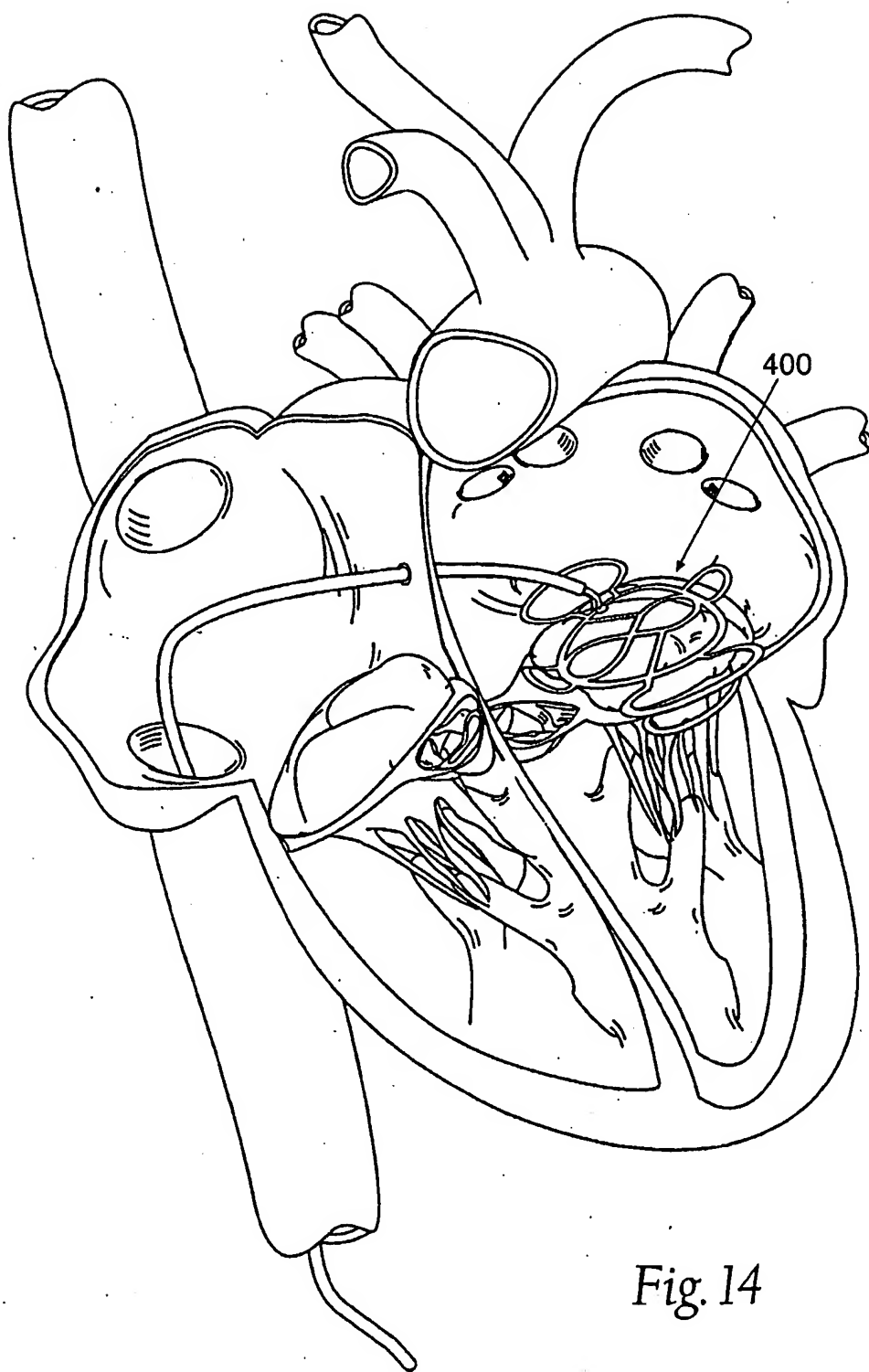
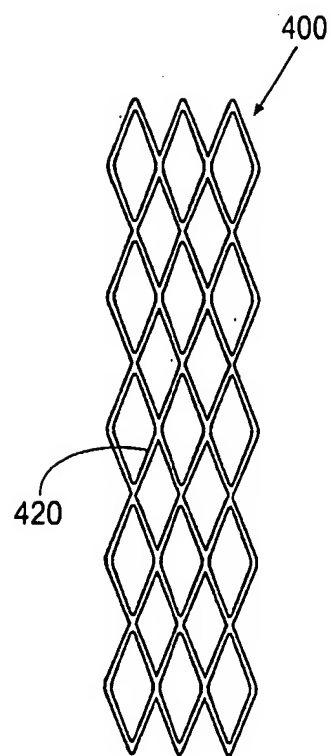
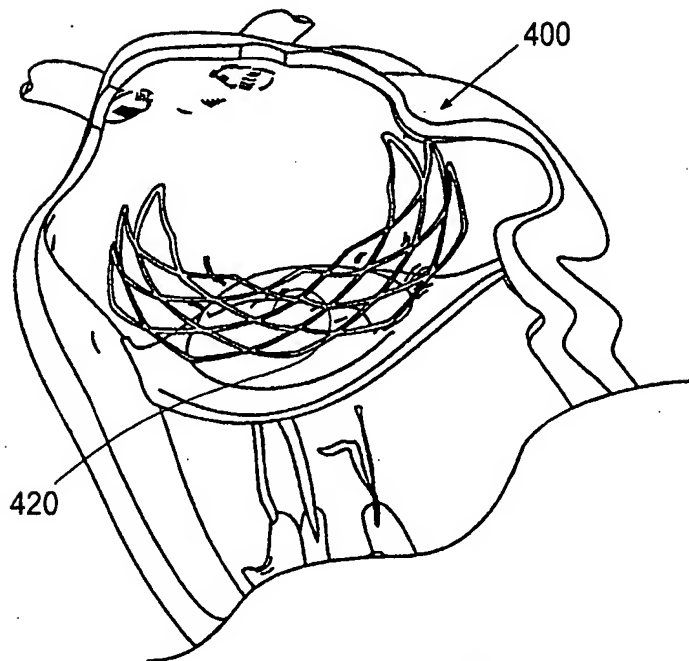
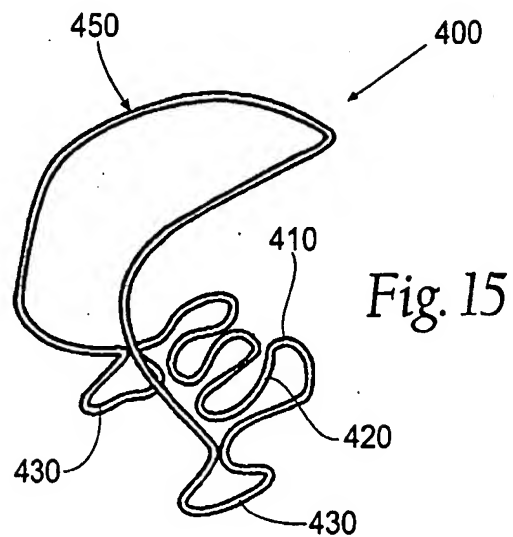


Fig. 14

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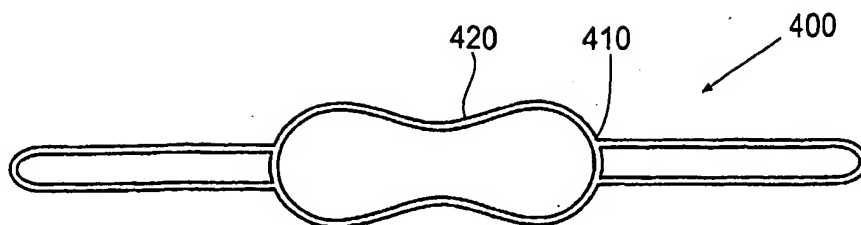


Fig. 18

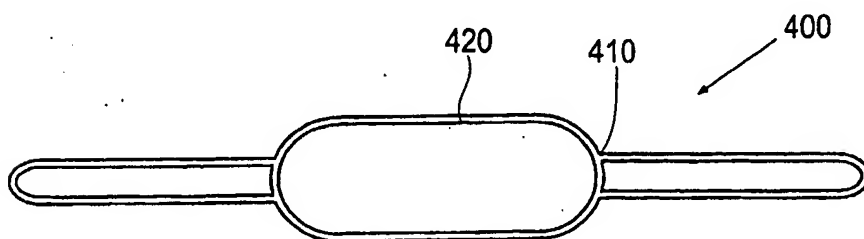


Fig. 19

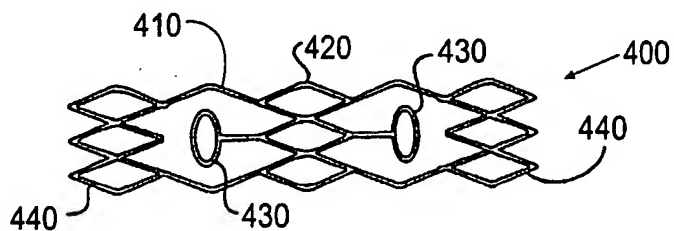


Fig. 20

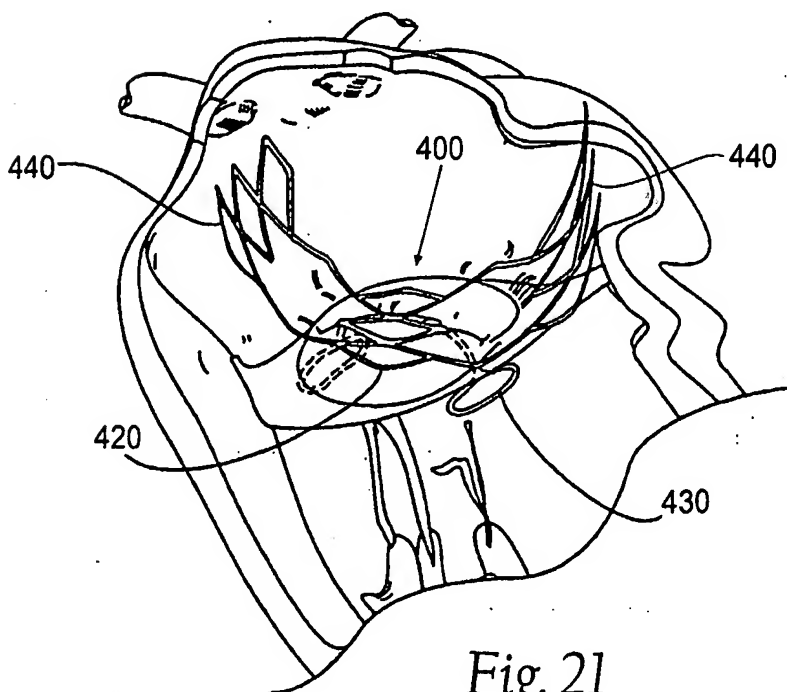


Fig. 21

Fig. 22

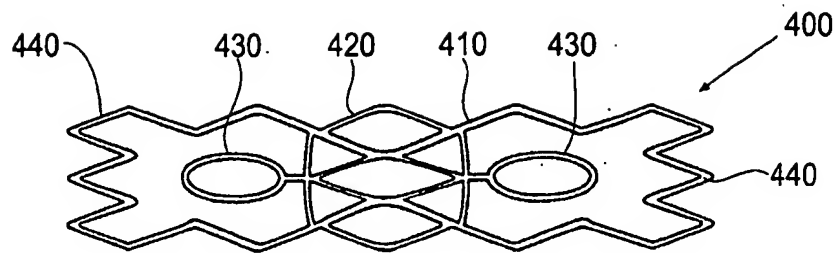


Fig. 23

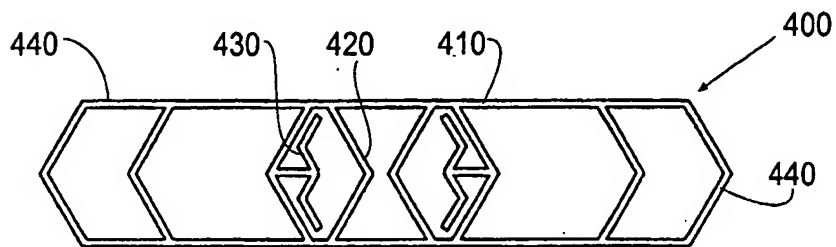


Fig. 24

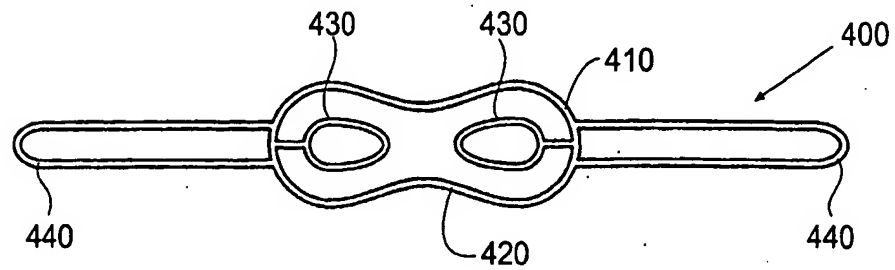
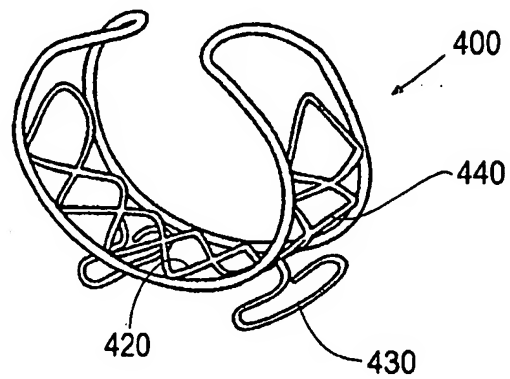


Fig. 25



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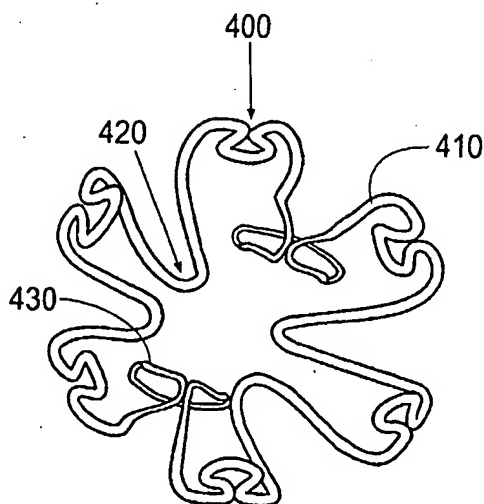
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(54) Title: **DEVICES FOR RETAINING NATIVE HEART VALVE LEAFLET**



(57) Abstract: Devices (400), systems and methods retain a native heart valve leaflet to prevent retrograde flow. The devices (410), systems, and methods employ and implant that in use rest adjacent a valve annulus and includes a retaining structure (420) that is sized and shaped to overlay at least a portion of one or more native valve leaflets. The retaining structure retains the leaflet or leaflets it overlays to resist leaflet eversion and/or prolapse. In this way, the implant prevents or reduces regurgitation. The implant does not interfere significantly with the opening of and blood flow through the leaflets during periods of antegrade flow.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/30833

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/24

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/2.1, 2.14, 2.16, 2.18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,454,799 B1 (Schreck) 24 September 2002, (24.09.2002) col. 5-13, and figures 1 and 7	1-18
Y	US 2002/0138138 A1 (Yang) 26 September 2002 (26.9.2002), sections. [0051-0103].	1-8
Y	US 2002/0123802 A1 (Snyders) 05 September 2002 (05.09.2002), sections [0037-0084]	1-18
Y	US 2001/0021872 A1 (Bailey et al.) 13 September 2001 (13.09.2001), sections [0046-0075]	1-18
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Date of the actual completion of the international search

24 March 2004 (24.03.2004)

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